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June 21, 2002

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RE: DOCKET ID NO. OEI-10014, COMMENTS ON DRAFT ``INFORMATION QUALITY GUIDELINES''

The following comments on the U.S. Environmental Protection Agency's draft "Information Quality Guidelines" are submitted on behalf of People for the Ethical Treatment of Animals (PETA) and our 750,000 members who are concerned about the suffering of animals in laboratories and Earth Island Institute, an environmental protection organization with 100,000 members.

Our organizations would be extremely pleased to see these guidelines followed with regard to the data upon which the EPA bases its regulatory decisions. Unfortunately, our experience to date with the EPA is so far from this stated goal that we find it hard to believe that "business as usual" will not continue to be norm even following the finalization of these guidelines. This concern is reinforced by the agency's demonstrated reliance on, and support of, non-validated test methods.

Nonetheless, these comments include suggested revisions to the proposed guidelines which, if implemented, would address some of our concerns as well as aid the agency in achieving the laudable goal of dissemination of quality information. EPA has specifically requested comments on its definitions of influential information, reproducibility of data, influential risk assessment, sources of information disseminated by the agency, and complaint resolution.

DEFINING INFORMATION QUALITY

The draft guidelines state that "quality" consists of *"objectivity, utility and integrity, of disseminated information. Objectivity, integrity, and utility are defined here, consistent with the OMB guidelines. 'Utility' refers to the usefulness of the information to the intended users. 'Objectivity' focuses on whether the disseminated information is being presented in an accurate, clear, complete, and unbiased manner, and as a matter of substance, is accurate, reliable, and unbiased."*

As noted above, the actual implementation of this section would signify an extreme reversal in the EPA's current approach to its responsibility to ensure the quality of data on which it bases its decisions.

For example, in 1999 we provided the EPA with documentation that several non-animal genetic toxicity tests were more sensitive than the animal test the EPA was requiring in its high production volume (HPV) chemical-testing program and that, for this reason, the *in vitro* tests were required by such countries as Germany and the United Kingdom. EPA officials paid no attention to our documentation until a grassroots campaign directed at the White House forced them to reconsider and reverse a 15-year policy of requiring the less sensitive animal test. Similarly, the EPA disregarded documentation we provided regarding a non-animal acute toxicity test that is 86 percent predictive of acute lethality in humans as opposed to the 65 percent predictivity to human mortality of the animal tests the EPA is currently requiring.

Just this past month, the EPA threatened to block an international consensus to allow non-animal skin corrosivity tests to be used as "stand-alone" methods. The EPA proposed that a non-validated animal test be used to "confirm" the results of the stringently validated and internationally accepted non-animal test methods. These examples point to a complete lack of objectivity on the part of decision-makers at the EPA who are responsible for data quality. Given that the internationally accepted criteria for test method validation (see section 3.4 below) includes documenting reproducibility as well as relevance, an objective perspective would automatically favor validated tests over non-validated ones. Since no animal test has ever undergone formal validation to establish its reliability and relevance to human health effects, it is unthinkable that such methods would be given any weight in – much less comprise the bulk of – the EPA's approach to assessing hazard and risk. An objective stance would exhibit a strong preference for the use of validated test methods. Yet the EPA adamantly pursues a double standard of preferring data obtained from non-validated animal tests.

EPA cannot achieve the standards set forth in Section 2 unless and until it requires that all animal test methods are validated using internationally-accepted criteria, and abandons those methods which cannot meet the criteria. Thus, we request that the guidelines be modified to compel such validation.

ENSURING AND MAXIMIZING INFORMATION QUALITY

The EPA provides a lengthy definition of "influential information" that would be subject to the guidelines' higher standard of quality. This definition includes *"information disseminated in support of top Agency actions (i.e., rules, substantive notices, policy documents, studies, guidance) that demand the ongoing involvement of the Administrator's office and extensive cross-Agency involvement; issues have the potential to result in major cross-Agency or cross-media policies, are highly controversial, or provide a significant opportunity to advance the Administrator's priorities. May also include precedent setting or controversial science or economic issues."*

Again, experience has shown us that absolutely major programs that involve tremendous amounts of resources (both in terms of financial costs and animal suffering and lives) have completely bypassed any external oversight of information quality. The EPA's HPV program is a case in point. We encourage the agency to move forward with its expressed intention to ensure the quality of all information which is key to reasoned decision-making.

In Section 3.3 the EPA states that *"influential scientific, financial, or statistical information should be subject to a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties, to an acceptable degree of imprecision. It is important that analytic results have a high degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed.*

It is also important that the degree of rigor with which each of these factors is presented and discussed be scaled as appropriate, and that all factors be presented and discussed. In addition, if access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should to the extent practicable, apply robustness checks to analytic results and document what checks were taken. Original and supporting data may not be subject to the high and specific degree of transparency required of analytic results; however, EPA should apply relevant Agency policies and procedures to achieve reproducibility to the extent practicable, given ethical, feasibility, and confidentiality constraints. EPA has several Agency-wide and Program- and Region-specific policies and processes which the Agency applies to ensure and maximize the quality of influential information. Agency-wide processes of particular importance to ensure the quality, objectivity, and transparency of influential information are the Agency's Quality System, Action Development Process, Peer Review Policy, and related procedures. Many influential information products may be subject to more than one of these processes."

The animal protection community has had a dismal experience with lack of data and procedural transparency at the EPA. This experience began in November 1998 when PETA learned of the HPV program. We were informed of the program by a PETA member who received a mailing from the Environmental Defense Fund (EDF) – the prime champion and architect of the HPV program. To our consternation, we quickly learned that no *Federal Register* notice had ever been published to inform interested stakeholders about the HPV program (a *Federal Register* notice was published *two years after* the implementation of the program) and no peer review or solicitation of public input had occurred. In clear disregard of the agency's 1981 policy on public participation, the HPV program had been developed quietly, behind closed doors, between three organizations – the EPA, the EDF, and the Chemical Manufacturers Association. Obviously, this approach flies in the face of the core concept of participatory government and transparency.

The HPV program is costly both in terms of dollars and animals' lives. The program is a waste of taxpayer money that calls for senseless, excessive tests on animals that offer nothing to the advancement of public health. According to the original HPV framework, chemical manufacturers "volunteer" to evaluate various industrial/TSCA chemicals. They pledge to review all existing data and use non-animal test methods to minimize unnecessary tests. However, we have reviewed each test plan as it has been submitted and regret to find that many of the test plans adhere to the EPA's demand for check-the-box toxicology rather than to good scientific principles of thoughtful toxicology.

Another major flaw of this program – which would have been corrected had the program been subjected to a transparent process and peer review – is that exposure data are not considered, which means it will be impossible to interpret data from the HPV program in a meaningful "real world" context. The underlying assumption of the program is that substances produced in large quantities automatically lead to high exposures. This has not proven true. Some compounds break down immediately when released into the environment and therefore do not present a hazard. Others, such as petroleum gases, are found in ambient and occupational environments at levels orders of magnitude below exposure limits. Several of the chemicals proposed for testing, such as p-cumylphenol and tris(nonylphenyl) phosphite, are already regulated by the Food and Drug Administration (FDA). Furthermore, chemicals like propane and butane are labeled "Generally Recognized as Safe" (GRAS) by the FDA, but industries plan to kill many more animals to further test these well-characterized substances in order to check the EPA's testing boxes. Testing has been proposed, and approved by the EPA, for a component of cinnamon oil on fish. Even components of fish oil will be tested on fish according to one EPA-approved testing plan. So will insoluble materials.

Despite the agency's claim that there are already a number of safeguards in place to "ensure and maximize the quality of influential information," the animal protection community has seen none of those safeguards actually implemented.

Other examples include the agency's blatant double standard with regard to the validation of animal versus non-animal tests (see information under section 3.4 below). Despite the unanimous recommendations of two government panels that the EPA subject the proposed animal tests in its massive endocrine disruptor screening program (EDSP) to the same rigorous scrutiny that the non-animal tests will undergo through the Interagency Coordinating Committee for the Validation of Alternative Methods (ICCVAM), the EPA ignored this advice and proceeded with a bifurcated approach to validation of tests, with a much lower standard for the proposed animal tests. Despite our repeatedly bringing this inconsistency to the attention of the agency, no one in management has been in any way responsive to this major data quality concern.

Another case in point is the EPA's requirement of a crude and non-validated test known as the developmental neurotoxicity test (DNT). This test, which kills as many as 2,000 animals every time it is conducted, has never been subjected to anything remotely approximating validation. EPA officials have admitted they do not know how to interpret the results of the test, yet the agency, under pressure from environmental organizations such as the Natural Resources Defense Council and the World Wildlife Fund, continues to require it (see pages 12-13 for further details).

The Voluntary Children's Chemical Evaluation Program (VCCEP) is also moving forward in which the EPA proposes to use crude, outdated, and non-validated tests on animals to establish levels of toxic contaminants that children should be expected to tolerate. The DNT is apparently an integral part of the VCCEP.

The EDSP is another massive EPA plan to test up to 80,000 chemicals on as many as 1.2 million animals for every thousand chemicals tested. Yet, the EPA has been unable to agree on the

definition of an endocrine disruptor, what health endpoints should be evaluated, or the experimental protocols. International scientists have denounced the proposed testing as "blindly stupid" and "appalling toxicology" [Third World Congress on Alternatives and Animal Use in the Life Sciences, Bologna, Italy, 1999]. Furthermore, the EPA is planning to apply tests that have not even been properly validated (see page 4).

We agree with the EPA's statement that *"[i]t is important that analytic results have a high degree of transparency regarding (1) the source of the data used, (2) the various assumptions employed, (3) the analytic methods applied, and (4) the statistical procedures employed.* We sincerely hope that EPA intends to reverse course and demand full transparency.

Section 3.4 discusses the manner in which the *"EPA ensure[s] and maximize[s] the quality of 'influential' scientific risk assessment information. In its dissemination of human health risk assessments that have been categorized as influential, EPA should ensure that the risk assessment adheres to the quality principles listed below. In applying these principles to human health risk assessments, the nature of the risk assessment will depend upon the information available, the regulatory application of the risk information, and the resources (including time) available. The level of effort and complexity of detail of a risk assessment should balance the information needs for decision making and the effort needed to develop such information. With respect to influential scientific information regarding human health risk assessments, EPA should ensure, to the extent practicable and in conformance with Agency guidelines, the objectivity of this information disseminated by the Agency by adapting the quality principles found in the SDWA Amendments of 1996:*

(A) The substance of the information is accurate, reliable and unbiased. This involves the use of, (i) the best available, peer-reviewed science as appropriate, and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).

(B) The presentation of information on human health effects, is comprehensive, informative, and understandable. In a document made available to the public, EPA should specify – (i) each population addressed by any estimate of applicable human health effects; (ii) the expected human health risk or central estimate of human health risk for the specific populations affected; (iii) each appropriate upper-bound or lower-bound estimate of human health risk; (iv) each significant uncertainty identified in the process of the assessment of human health effects and studies that would assist in resolving the uncertainty; and (v) peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support any estimate of human health effects and the methodology used to reconcile inconsistencies in the scientific data.

In applying these principles, "best available" refers to the availability at the time an assessment was made, and that in some situations, the Agency may need to weigh the resources needed and the potential delay associated with gathering additional information in comparison to the value of the new information in terms of its potential to improve the substance of the assessment. In an effort to expand these guidelines to apply to environmental and safety-related

risk assessments, the Agency intends to seek input from appropriate stakeholders and the scientific community."

The U.S. animal protection community respectfully draws your attention, yet again, to the EPA's glaring lack of interest in data quality where animal test methods are concerned. In its animal welfare factsheet, the EPA states: "Scientific validation is an essential step in determining the adequacy of new alternative test methods." The EPA insists that rigorous validation is critical for non-animal test methods, yet it vehemently resists applying the same scientific standards to its animal test methods. Clearly, *all* test methods intended for regulatory risk assessment purposes—whether *in vitro* or *in vivo*—must be held to the same standards of scientific validation to ensure their relevance and reliability. Anything short of this results in the proverbial "garbage in, garbage out" and constitutes arbitrary action by the agency.

Criteria for test method validation emerged from an international conference convened in 1996 in Solna, Sweden, by the Organization for Economic Cooperation and Development (OECD). The resultant "Solna criteria" have since become *the* internationally accepted standard by which a test's validity is judged. Validation means documenting that the test method is reliable, reproducible, and relevant. Yet despite the EPA's rigid requirement that all new or revised non-animal test methods be formally validated according to the Solna criteria, the agency maintains an unacceptable double-standard by continuing to accept and require the use of animal-based tests which have never been validated (according to any current understanding of the term), and the reliability and relevance of which are so limited that they likely would not satisfy the validation criteria in place today. For example, the Multicenter Evaluation of *In Vitro* Cytotoxicity (MEIC) study examined rat and mouse LD50 data and found that these tests were, at best, 65 percent predictive of acute toxicity in humans (as measured by lethal peak bloodstream concentrations obtained from cases of acute poisoning).

Another example is that of the Draize eye irritancy test. In 1971, Weil and Scala studied the reproducibility of the standard rabbit eye irritation test. They concluded that due to the significant variability in results from day to day and lab to lab, the Draize eye test should not be recommended as a standard procedure for regulatory use. Yet this test continues remains in routine use worldwide, even to this day. In 1986, Freeberg and colleagues studied 281 cases of accidental human eye exposure to 14 household products, and compared the outcome with pre-existing Draize test data. The results were highly variable, and the correlation coefficient between rabbit and human eye responses was only 0.48. This suggests that toxicologists might be better off tossing a coin to identify chemicals that are human eye irritants. A few years later, Koch and colleagues at the U.S. Food and Drug Administration stated that there was no clear relationship between the rabbit eye response and the exposure of the human eye to chemicals or products, and that the Draize test is "plagued" by lack of reproducibility.

Likewise, animal data from long-term animal tests such as for carcinogenicity are difficult to confirm or contradict. Human data are sparse, and where cases of cancer occur, they can be very difficult to link to a particular chemical exposure. Because rats and mice have short lifespans and a statistically significant result is desired, animals are dosed with many times the likely exposure humans would experience over a much longer lifespan. Then, to try and account for this and other differences, such as those due to species variations, guesstimate "uncertainty factors" are

applied to the results. Where comparative studies have been undertaken, rodent carcinogenicity tests have been found to lack relevance and reproducibility. For example:

-- they produce an unacceptable number of false positive results (e.g., 19 of 20 substances believed to be safe in humans had been carcinogenic in rodents);
-- 46% of substances were found to have been carcinogenic in rats but not in mice, and vice versa;
-- of 19 known human carcinogens, rodent tests had identified only 37%;
-- a very recent analysis of duplicate rodent carcinogenicity data showed that there was only a 57% agreement between results for 121 chemicals, each of which had been tested on two occasions.

While we are cognizant of the strong belief among regulators at the EPA that *in vivo* tests are intrinsically more relevant than *in vitro* and other non-animal methods, there is no *a priori* reason why this should be so. Indeed, given the modest predictive accuracy of even such mainstay animal tests as those for acute toxicity, eye irritancy and carcinogenicity, it cannot simply be assumed that data derived from tests in one animal species are *de facto* relevant to another species. In fact, far from providing an unequivocal assessment of chemical risks to humans, the relevance of data derived from unvalidated animal tests is always in question, and therefore subject to vastly differing interpretations, and often, successful legal challenges.

The introduction of the EPA's revised guidelines for carcinogenic risk assessment states that the purpose and scope of the document is to "encourage both regularity in procedures to support consistency in scientific components of Agency decision making and innovation to remain up-to-date in scientific thinking". Unfortunately, the revised guidelines, in their current form, provide a clear of example of data quality that does not come close to meeting the stated objective to "remain up-to-date," in that they continue to promote the use of unvalidated animal tests which are fraught with scientific limitations in terms of their reliability and relevance to humans. The EPA's acknowledgement that "a higher level of confidence is generally given to data that are derived from *in vivo* systems," while currently true, demonstrates its obvious and continuing bias in favor of animal testing that is both scientifically and ethically indefensible in light of the available scientific evidence.

Lave *et al*. have concluded that "the [rodent carcinogenicity] bioassay does not provide information commensurate with its cost, implying that regulatory policies of industrialized countries need to be changed" [Lester LB, Ennever FK, Rosenkranz HS & Omenn GS. "Information value of the rodent bioassay," *Nature* 336(6200):631-3]. Similarly, NIEHS deputy director, Dr. Richard Griesemer, has stated that "animal research, by itself, should no longer be accepted as a reliable means of judging risks for humans," and the NIEHS director's expert review committee concluded that "the government should no longer rely on animal studies" [*New York Times*, "Many Say Lab Animal Tests Fail to Measure Human Risk," 3-23-1999]. We could not agree more and if the EPA were to adhere to strict data quality criteria rather than to its outmoded and knee-jerk preference for animal tests, public health and the protection of the environment would benefit.

The EPA's continued acceptance of unvalidated – and clearly flawed – animal studies

undermines the credibility of its risk assessments, and violates the direction given by Congress for federal agencies to implement systems of decision-making that are based on sound science. To quote Dr. Michael Balls, head of the European Centre for the Validation of Alternative Methods: "What would be the value of the data such tests would provide, and with what confidence could they be applied in making decisions?" [*ATLA* 1999, Vol. 27].

Frequently, the EPA's lack of data quality is so obvious that it would be laughable if it did not also mean so much suffering for so many animals. A very recent case in point can be seen in the document "A Review of the Reference Dose and Reference Concentration Processes." Table B-4, page B-22, of this document lists an uncertainty factor of 3 when extrapolating from rats to humans (interspecies extrapolation) and an uncertainly factor of 10 when extrapolating from human adults to human children (intra-species extrapolation). This lack of use of even the most basic common sense is unfortunately all too prevalent among EPA assumptions and hinders any attempt at real data quality.

Once again we suggest that EPA cannot achieve dissemination of quality information without a mandate that internationally accepted criteria for validation be applied to all test methods, *in vivo* and *in vitro* alike. Thus we request that the proposed guidelines be revised to include such a mandate.

PEER REVIEW

The indisputable fact remains that a massive EPA program such as the HPV chemical-testing program was implemented without the least attempt at peer review. The studies upon which this program was developed and based were never subjected to any review (see "Toxic Ignorance or Toxic Terror" by Spitzer and Wilson, included as part of the Congressional record for the June 17, 1999, hearing of the Subcommittee on Energy and the Environment on the EPA's High Production Volume Chemical Testing Program, U.S. Government Printing Office ISBN 0-16-059407-3).

If EPA is going to, as we think they should, eliminate panelists with actual or potential conflicts of interest, it must include as an area of conflict the vested interested of many panel members in animal-based toxicology. In addition to the obvious conflicts of interest that others have commented on, we note that EPA review boards are consistently devoid of panelists with expertise in anything beyond animal toxicology. Many EPA panelists have obvious ties to the animal testing industry and stand to benefit from the agency's continued almost exclusive reliance on animal testing methods.

The requirement for membership on advisory boards should be revised to address this area of conflict as well. In addition, it is worth noting again that animal protection organizations have been completely excluded from all but one of the agency's advisory committees. While industry and environmental organizations are amply represented and welcomed, we had to fight for the belated placement of even one eminently qualified expert on the former endocrine disrupter standardization and validation taskforce.

CORRECTION OF INFORMATION

Section 5 deals with the correction of information and the complaint resolution process. *"EPA has developed a complaint resolution process. That is, your initial complaint would be heard by what EPA calls the 'information owner'. That 'information owner' is the EPA person designated by management in the EPA program, or who has the responsibility for the quality, objectivity, utility and integrity of the information disseminated by EPA. Next, should you appeal the initial decision, your appeal would be heard by the Assistant Administrator (AA) or Regional Administrator (RA) for that program or region. The AA and RA are the highest ranking official for those organizations. They are political appointees. That appeal would be decided in collaboration with a standing panel. That panel would consist of other AAs and RAs to ensure that your appeal is taken to a most senior level right away. The EPA Chief Information Officer would chair that panel. There are many more details that EPA has yet to decide and the Agency encourages your input as it develops this proposal."*

If this procedure is implemented as described, we can expect nothing more than the continuation of the EPA's current stonewalling of our data quality concerns. To assign a review of the problem to the EPA staff in charge of the particular issue or program is to have the proverbial fox guarding the hen house. Our data quality concerns have been repeatedly met with a complete lack of interest on the part of the staff and management responsible for the issue of concern. Everything begins and ends with the "information owner," as individual bureaucrats have tremendous power to indefinitely delay a review of our concerns. It has been our experience that even an administrative assistant, whose attention we have received only when our grassroots campaigns make enough waves for the agency, is no more inclined to challenge the accepted norm at the agency than are his or her staff people.

Therefore it is critical that the review include officials from outside the fiefdom in which the conflict is occurring, i.e., an objective review will require the involvement of individuals outside the agency. Thus, we suggest that an independent panel of experts, which is balanced and free of members who have conflicts of interest, be established to review requests for correction of information. Selection of the members for such a panel must be subject to public notice and comment.

Moreover, due to the extreme delays in EPA's responses to concerns and requests addressed to the agency in other contexts (such as requests pursuant to the Freedom of Information Act), we suggest that EPA establish a specific response time in the guidelines. Such a deadline will serve the duel purpose of ensuring that concerns of the public are addressed in a timely manner and that agency action is not unduly delayed.

Section 5.2 provides that *"[a]ny individual or person may request a correction of information from EPA, if that individual or person is an 'affected person'*
for the purposes of these guidelines, 'affected persons' are persons who may benefit or be harmed by the disseminated information. This includes persons who are seeking to address information about themselves as well as persons who use information."

In the past, EPA, industry, and environmental organizations have actively sought to preclude the animal protection community from any means to contribute to and/or review the development of EPA test methods and to gain review of consequent agency actions. PETA stands at the forefront of animal protection organizations that scrutinize the cruel and unnecessary use of animals in laboratories. For example, as one of four program areas on which PETA focuses its resources, the organization spends tens of thousands of dollars annually on the issue of animal experimentation with a large portion of this budget targeted specifically for EPA-related programs.

For these reasons and others, there can be no doubt that PETA and other animal protection organizations are "affected" by the EPA's continued reliance on the use of animals in non-validated tests and, as such, we may request corrections to information disseminated by EPA as set forth in the guidelines. However, from past experience we know there will always be entities and individuals – specifically, those threatened by our position on the issue of animal testing – who dismiss the harm suffered by animal protection organizations and seek to prevent our involvement in any manner. Thus, we request that EPA acknowledge the harm to the animal protection community in the guidelines and revise the definition of "affected persons" to expressly include such organizations. Such a revision will avoid what are likely to be repeated, lengthy disputes over the right of the animal protection community to protect its interests and the interests of the millions of animals suffering in laboratories.

Section 5.4 deals with the requests for correction of information that the agency will and won't consider. Examples of requests that the agency will not consider include those that *"pertain to EPA actions, where a mechanism by which to submit comments to the Agency is already provided. For example, EPA rulemakings include a comprehensive public comment process and impose a legal obligation on EPA to respond to comments on all aspects of the action. These procedural safeguards assure a thorough response to comments on quality of information. EPA believes that the thorough consideration required by this process meets the needs of the request for correction of information process. A separate process for information that is already subject to such a public comment process would be duplicative, burdensome, and disruptive to the orderly conduct of the action. If EPA cannot respond to a complaint in the response to comments for the action (for example, because the complaint is submitted too late to be considered along with other comments or because the complaint is not germane to the action), EPA will consider whether a separate response to the complaint is appropriate. EPA may consider frivolous any complaint which could have been submitted as a timely comment in the rulemaking or other action but was submitted after the comment period."*

With regard to the exemption proposed for programs that are undergoing rulemaking, with their concomitant comment periods, we must point out the following:

(1) In some cases, issues of data quality appear to be part of a rulemaking but are, in fact, adopted without any public notice or opportunity to comment. An example of this is the December 15, 2000, promulgation of the Toxic Substances Control Act Test Guidelines as a final rule. The developmental neurotoxicity test described above was subsumed in this rule under a larger set of testing regulations with no opportunity for comment, even though the

EPA was fully aware of the scientific and data quality questions regarding this particular test method.

(2) EPA has a tendency towards long delays in comment review and promulgation of final standards. An example is the rule for dermal absorption testing using an *in vitro* method that was proposed following a request from the Occupational Safety and Health Administration to the Interagency Testing Committee more than a decade ago. EPA published its proposed rule in June 1999. Even though the proposal was non-controversial, the EPA has yet to issue the final rule more than three years later! As a result, the EPA continues to require the use of animals in painful testing procedures for dermal absorption and, under the proposed guidelines, we still would have no opportunity to challenge this arbitrary and capricious method of data gathering.

(3) Lastly, a problem will exist with "complaints submitted too late," since much of the data that is of dubious quality has been gathered in the same fashion for years. For example, the EPA continues to require the use of animals in metal bioavailability testing. Non-animal approaches to the accurate assessment of metal bioavailability have been available and in widespread use since 1994, and can be conducted for a small fraction of the cost of animal tests. The agency has been unresponsive to these concerns and we thus request that EPA ensure a means to challenge information which was disseminated prior to the Act's effective date but which EPA continues to rely upon in the present.

We also request that EPA further define criteria to be used for determining whether a request is deemed "frivolous" and thus exempt. The present criteria, which include a request "made in bad faith or without justification" or a request which is "inconsequential or trivial," are extremely subjective. Given the fact that EPA has been less than receptive to the information submitted by the animal protection community, we are concerned that this vague exemption will provide officials with the means to summarily dismiss legitimate requests for correction of information. Although we understand the desire to eliminate wasteful reviews, certainly the exemption can be tailored more narrowly to avoid the potential for abuse by either the agency or the requester.

Section 5.5 provides that "*EPA may elect not to correct some completed information products on a case-by-case basis due to Agency priorities, time constraints, or resources*." PETA and EEI strongly question why the agency would choose to disseminate information which has been proven to be inaccurate. Such an exemption runs counter to the very purpose of the Data Quality Act and to EPA's own stated goal.

Section 5.7 provides a process for requests for reconsideration of EPA decisions. We have the same concerns about the objectivity of an "executive review panel" which is composed of EPA officials and others with a vested interest in maintaining the status quo as well as the open-ended time frame for such an appeal, as discussed above with regard to the initial request for review (see pages 10-11).

CONCLUSION

PETA and EEI maintain that certain mainstream environmental organizations are just as guilty as industry in attempting to conduct closed-door business with a regulatory agency and in pushing biased science that is not subject to peer review. For example, the World Wildlife Fund (WWF)

representative tried to exclude animal protection representatives from the endocrine disruptor standardization and validation taskforce when we attempted to gain observer status. This taskforce was immediately disbanded once we challenged its closed-door nature, but it had been operating in such a fashion for a number of months before we became aware of its existence.

At the 18th international neurotoxicology conference in Colorado Springs, Colorado, a panel of experts assembled to review the developmental neurotoxicity test agreed that they could not determine if the results were relevant to humans. In response to a question regarding a National Academy of Science report which stated that the EPA needed to justify why it was using the rat as the model in this test, EPA official Deborah Rice responded as follows: "We know the rat is not the right model. But it's like being in a bad marriage – you know you should get out but you don't because there's too much history there." The chief scientist for the Natural Resources Defense Council agreed that conducting the test "was better than nothing."

We strongly disagree. Not only do 2,000 animals suffer and die every time this test is conducted, the results from this non-validated test are meaningless as a basis upon which to regulate hazardous substances. We see this impasse occurring over and over again with environmental groups and the EPA.

The latest example in a long string of ineffective actions on the part of the agency in charge of protecting the public health can be seen in its attempts to regulate the pesticide atrazine. According to recent media reports, the EPA has epidemiological data from humans showing a link between exposure and cancer. Yet "the agency's deliberations are especially complex because they are based on experiments with laboratory animals that imperfectly model the way chemicals like atrazine affect humans" (*New York Times*, 6-6-02).

After years of study, and many hundreds of animals tests, the EPA has decided that the rat study is not relevant to humans and has "determined that the mode of action for the carcinogenic potential in the Sprague-Dawley rat is not likely to be operative in humans," that "there is strong evidence that the mechanism by which atrazine increases the incidence of mammary gland tumors in SD rats is not relevant to humans," and that "there are considerable differences between the hypothalmic-pituitary-ovarian function in rats and humans" [Atrazine: *Response to Public Comments on the EPA's January 19, 2001, Revised Preliminary Human Health Risk Assessment and Associated Documents for the Reregistration Eligibility Decision*, 4-16-02]. Yet the EPA's entire endocrine disruptor screening program—which will inflict suffering and death upon tens of millions of animals— is based entirely on the application of rodent endocrine tests to humans. If the EPA has now decided, after countless thousands of animals suffered and died to test atrazine, that those tests are not applicable to humans, one would assume that this would pose extensive problems when it comes to interpreting the masses of data that will be generated by the EPA's other animal-testing programs.

Because animal tests are not validated and are so unreliable, their results can be easily manipulated by either side. In this case, industry charges that "NRDC is misusing preliminary data on frogs" (*Daily Environment Report*, 6-4-02) and vows to "offer studies of its own to refute the frog research" (*New York Times*, *ibid.*). The arsenic scenario is thus repeating itself with atrazine. Epidemiological studies linked arsenic to cancer in humans for decades; yet the EPA

continued to kill animals in tests that attempted to reproduce the effects already seen in human. Recently, the EPA spent $400,000 of our tax money to subject animals to more mercury inhalation studies in an attempt to duplicate the reproductive effects already documented in dental workers. Of the results, the chief researcher states, "We weren't able to reproduce any of those effects in our animal model" (*Environmental Health Perspectives*, Vol. 108, April 2000).

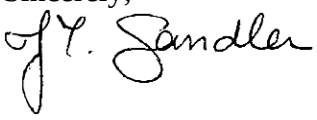
Until the EPA uses and demands the use of reliable, reproducible, and relevant validated test methods, data quality will be but a fantasy and this scenario will keep recurring, animals will continue to suffer and die in useless and out-dated test methods, and neither the public health nor the environment will be protected.

WWF recently charged that an initiative to better understand human exposure to chemicals would "give chemical manufacturers undue influence" (*Daily Environment Report*, 6-17-02). However, it is apparently appropriate for such environmental groups as Environmental Defense to work hand in glove with the EPA to develop a massive animal-testing program that was never subject to the slightest peer review (HPV) and for WWF to take large amounts of money themselves from industry organizations to subsidize research into endocrine disruptors. Environmental organizations have an agenda to push with the EPA as much as industry and trade associations do. And they are just as likely to stoop to poor science, to manipulation of data, and to excluding other stakeholders from input, as industry is.

The only solution is for the EPA to adhere to strict standards of transparency, data quality, an even-handed approach to the validation and acceptance of test methods, and to leave in the trash heap of history its traditional double standard with regards to *in vitro* test methods. However, if history is any guide, the EPA's implementation of the Data Quality Act will not result in any significant improvements in the agency's current *modus operandi*.

While the goals of the Data Quality Act are admirable, it is highly doubtful that the EPA will effectively implement it. The need for support of this policy at the highest levels of the agency is obvious. It is only when top management officials commit themselves to a policy of openness, forthrightness, and quality science, and require the same of their staff, that the American public will actually benefit from this legislation. Unless such a commitment is made and enforced through strict review and inclusion in performance appraisals at all levels, the EPA's implementation of the Data Quality Act will lack substance and will remain only words on paper.

Sincerely,



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